Prelinguistic communication: how do children communicate before formal language

Who is eligible: parents of children
- definite CHARGE syndrome (is your information in CSCDP?)
- under 22 years old
- fewer than 50 functional words or signs

How will the research be conducted at the conference?
First, you will be asked to complete a developmental questionnaire about your child's speech / language and hearing histories, as well as on augmentative and alternative communication techniques and adaptations which have been tried with your child. Next, you will be asked to complete a face-to-face interview. You will be asked about your child's use of communication signals, including vocalizations, facial expressions, body movements, and eye gaze--which are interpreted as meaningful communication. **Estimated time**: 45 - 90 minutes. **You can schedule an appointment NOW.**

To schedule an appointment at conference, contact Dr Susan Bashinski
sbashinski@missouriwestern.edu We will be wearing buttons saying "Ask me about Early Communication Development"

For more detailed consent information, read on:
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Missouri Western State University

Informed Consent to Participate in Research

(Information to consider before taking part in research that has no more than minimal risk)

Title of Research Study: ***Parent Report of Communication Ability in Individuals with CHARGE Syndrome***

Principal Investigator: Susan M. Bashinski, Ed.D.
Institution/Department or Division: MWSU, Department of Education
Office Address: 111 Murphy Building, Room M
Telephone Number: 816.271.5629

This consent form contains important information to help you decide whether or not to participate in a research study.

The study staff will explain this study to you. Ask questions at any time about anything that is not clear to you. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Participating in a study is voluntary – your choice.**

- **If you join this study, you may still decide to <u>stop at any time in the future</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research is being conducted
- What will happen during the study
- Any possible benefits to you
- The possible risks to you
- Other options you could choose instead of being in this study
- How your child's personal information will be treated during the study
- How your child's personal information will be treated after the study is over
- Whether or not participating in this study involves any cost to you
- What to do if you have problems or questions about this study.

<u>Please read this entire consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	
	First Name / Last Name		
Principal Investigator (PI)	Dr. Susan M. Bashinski	**Contact Phone #**	(816) 271.5629
	First Name / Last Name Credentials		
Title of Project:	Parent Report of Communication Abilities in Individuals with CHARGE Syndrome		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Susan M. Bashinski and colleagues because your child has been previously diagnosed with CHARGE Syndrome and does not communicate with many words.

This consent document may contain words that you do not understand. <u>Please ask the researcher or research staff to explain anything you do not understand</u>.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to describe communication abilities in individuals with CHARGE syndrome who have little to no natural speech. The majority of persons with CHARGE Syndrome experience significant communication disability

This study will enroll as many as 75 participants.

2. WHAT AM I BEING ASKED TO DO?

First, you will be asked to complete a developmental questionnaire about your child's speech / language and hearing histories, as well as on augmentative and alternative communication techniques and adaptations which have been tried with your child. Next, you will be asked to complete a face-to-face interview with one of the investigators. You will be asked to report on your child's use of potential communication signals, including: vocalizations, facial expressions, body movements, and eye gaze--which are interpreted as meaningful communication.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

The time you will be asked to spend for this research study is about 60 to 90 minutes. The developmental questionnaire will take about 15 minutes of your time. The face-to-face interview will take approximately 60 minutes of your time. You might be contacted to answer follow-up questions over the phone or through email (i.e., an additional 5 to 10 minutes of your time). For example, the researcher might contact you if you wanted to report some exact information that was not available to you at the CHARGE Conference, such as past audiological findings, or if discrepancies in some responses are noticed after the conference has concluded.

4. WHAT ARE THE RISKS?

Certain discomforts might occur if you decide to take part in this research study. These include that you may get tired answering questions, or that some of the questions may make you feel sad, as you reflect on your child’s development. If you experience any discomfort during the interview, Dr. Bashinski and other investigators will try to help you by skipping over a question, or inviting you to take a break, as needed. Every effort will be made to protect all data collected from you in this research study. A possibility for a breach of confidentiality does, however, exist. The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You will very likely not benefit directly from participating in this research study, though you will receive a summary of the communication assessment completed with you regarding your child’s communication skills. Even though you may not receive any direct benefit, others might benefit in the future because of what the researchers learn from this investigation.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose to not participate in this research study.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published, but neither your name nor your child's identity will be revealed; all of your records will remain private. In order to protect your information, Dr. Susan M. Bashinski will assign a number to your interview form; she will keep a list that links your name to the interview form on a separate computer drive. All interview forms will be kept in a locked office at Missouri Western State University. Data *without* your identifiers will be shared with Dr. Barbara Braddock at St. Louis University.

If you have, in the past, also participated in the CHARGE database project, your information will be shared with that project.

The Missouri Western State University Institutional Review Board (the group responsible for protecting the welfare of persons who take part in research) and other university officials may review your research study records. State laws or court orders may also require that information from your research records be released.

8. WHAT ARE THE COSTS AND PAYMENTS?

You will not receive payment for participating in the study. You should not, however, incur any additional or unexpected expenses by choosing to participate in this research study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you have any questions about your rights as a research participant or if you believe you have suffered an injury as a result of taking part in the research, you may contact the Director of the Committee on the Use of Human Subjects at Missouri Western State University (cronk@missouriwestern.edu), who will discuss your questions with you or will be able to refer you to someone else who will review the matter with you, identify other resources that may be available to you, and provide further information as how to proceed.

10. WHOM CAN I CALL IF I HAVE QUESTIONS?

The researcher conducting this study will be available to answer any questions concerning it, now or in the future. You are invited to contact Dr. Susan M. Bashinski, researcher at Missouri Western State University, at the email address or number listed below:

111 Murphy Hall, Room M
Missouri Western State University
4525 Downs Drive
St. Joseph, Missouri 64507
sbashinski@missouriwestern.edu
816.271.5629

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is totally voluntary. You may choose, at any time, to discontinue your participation in this research study. There will be no penalty to you if you choose to not take part. The research study staff will let you know of any new information that may affect whether or not you want to continue to take part in the study.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask all my questions and state any concerns. I have been asked if I wish to speak directly to the researcher responsible for this study. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent
I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

_____ _____
Consent Signature of Research Participant (18 and over) Date

_____
Print Name of Participant

MISSOURI WESTERN STATE UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL

This form is valid only if the IRB's approval is reported below.

Approved, May 21, 2015 – 12:28 PM
IRB #2331

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the participant has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	

NOTE: The Principal Investigator or Research Team Member who signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.